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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,640	01/04/2005	Stephan Fegert	FEGERT	3103
20151	7590	03/26/2007	EXAMINER	
HENRY M FEIEREISEN, LLC 350 FIFTH AVENUE SUITE 4714 NEW YORK, NY 10118			BOR, HELENE CATHERINE	
			ART UNIT	PAPER NUMBER
			3768	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	03/26/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

SOP

Office Action Summary	Application No.	Applicant(s)	
	10/517,640	FEGERT ET AL.	
	Examiner	Art Unit	
	Helene Bor	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 December 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-32 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 09/12/2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/03/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input checked="" type="checkbox"/> Other: <u>Journal article</u> |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 6, m1, m2 and m3. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "4" has been used to designate both a receiver and a evaluation unit. Also reference character "2" has been used to designate both a magnet and a magnet assembly. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application.
3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, "the drill, cutting or impact apparatus, at least one needle, and at least one set of forceps" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
4. The drawings are objected to because:
 - a. Cooling liquid or a gas not labeled in Figure 5 (Paragraph [0071])
 - b. Liquid needs a reference label in Figure 8
 - c. Laser needs reference label in Figure 9

- d. Wavy lines need reference label or explained in specification as to the nature of the lines in Figure 10
- e. Wavy lines need reference label or explained in specification as to the nature of the lines in Figure 10
- f. Wavy line needs reference label or explained in specification as to the nature of the lines in Figure 11
- g. Instrument 1 is disclosed as in use with Figure 12, however, it is not clear the relationship instrument 1 has with Figure 12. Instrument 1 should be shown in Figure 12
- h. Figure 13 is missing L

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claim 21 objected to because of the following informalities: It is unclear in the preliminary amendments whether or not the "a" is meant to be crossed out or not. As stated in the MPEP § 1.121(c)(2):

The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 provides for the use of obtaining endoscopic images for diagnostic purposes, obtaining electrical or electrophysiological data, examination of blood vessels and the treatment of vessel constrictions, carrying out and/or monitoring operative actions on the brain, heart or on the intestinal tract, implantation of organ and tissue

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spare parts, joint prostheses, electromagnetic probes and pulse transmitters, heart pacemakers, vessel spare parts and catheters, removal or destruction of gallstones or kidney stones, inflamed tissue, tumor tissue, bone or joint material, deliberate emission of therapeutic substances to debilitated tissue or tumor tissue, irradiation of tumor tissues, determination of the position, feed axis and roll angle in real time, measurement of the rotation rate or of a change in the rotation rate, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 29 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1-3, 5-8, 13-14, 17-20, 22-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuckes'755 (US Patent No. 5,258,755).

Claim 1: Kuckes'755 teaches an instrument having magnet producing a magnetic moment perpendicular to an axis of the instrument (Col. 6, Line 7-11). Kuckes'755 also teaches the magnet being rotatable independently of the instrument (Col. 10, Line 46-50).

Claim 2/1: Kuckes'755 teaches a receiver [magnetometer] which detects the three time-dependent magnetic field components (Col. 2, Line 60 – Col. 3, Line 24).

Claim 3/1: Kuckes'755 teaches an evaluation unit [computer] for determining parameters such as position (Col. 7, Line 39-46) or position of the instrument axis (Col. 9, Line 8-12).

Claim 5/1: Kuckes'755 teaches the instrument is mounted on a rotatable shaft (Col. 5, Line 63 – Col. 6 Line 4) defined by the instrument axis (Figure 2, Element 18) and a magnet being attached to the instrument shaft (Figure 2, Element 40).

Claim 6/5/1: Kuckes'755 teaches using a drive for rotating the magnet that is independent of the instrument shaft (Col. 10, Line 46-50).

Claim 7/6/5/1: Kuckes'755 teaches the drive being an electrical drive (Col. 10, Line 46-50).

Claim 8/6/5/1: Kuckes'755 teaches the drive is a hydraulic drive using liquid to drive the magnet (Col. 10, Line 41-46).

Claim 13/1: Kuckes'755 teaches the instrument having a drill or cutting apparatus (Figure 1, Element 32).

Claim 14/1: Kuckes'755 teaches the instrument has an opening for ejection of a liquid such as drilling fluid (Figure 5, Element 36).

Claim 17/1: Kuckes'755 teaches an apparatus [such as a computer] for recording electrical data (Figure 1, Element 24).

Claim 18/1: Kuckes'755 teaches using transmitters and receivers for processing signals to determine a position of the instrument at different points (Figure 1, Element 20 & Element 8).

Claim 19/18/1: Kuckes'755 teaches a transmitter constructed as a permanent magnet (Figure 1, Element 40) and configured to produce different frequencies, amplitudes and/or by the production of different analog or digital values (Col. 9, Line 35-59).

Claim 20/1: Kuckes'755 teaches a frequency modulation and/or amplitude modulation for variation of the magnetic field generated by the magnet (Col. 9, Line 35-59).

Claim 22: Kuckes'755 teaches a method of determining the location of an instrument (Abstract). Kuckes'755 teaches a rotating magnet to produce a magnetic moment perpendicular to an axis of the instrument (Col. 6, Line 7-11). Kuckes'755 teaches detecting three time-dependent magnetic field components of the magnetic field (Col. 2, Line 60 – Col. 3, Line 24).

Claim 23: Kuckes'755 teaches a method of determining the location of an instrument (Abstract). Kuckes'755 teaches producing a magnetic moment by a rotating magnet perpendicular to an axis of the instrument (Col. 6, Line 7-11) with the transmitter magnet connected to the instrument (Figure 3, Element 44 & Figure 2, Element 40).

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Kuckes'755 teaches detecting three time-dependent magnetic field components by a receiver (Figure 1, Element 20).

Claim 24/23: Kuckes'755 teaches a method of using data to determine a position, direction of the instrument axis and roll angle [instantaneous angular position] of the instrument from the data (Col. 7, Line 39-46, Col. 8, Line 18-38 & Col. 8, Line 68 – Col. 9, Line 12).

Claim 25/22: Kuckes'755 teaches a method for determining a distance and direction of two measurement points or measurement areas with respect to one another (Col. 7, Line 39-46).

Claim 26/22: Kuckes'755 teaches a method for frequency modulation for variation of the magnetic field generated by the magnet (Col. 9, Line 35-59)

Claim 27/26/22: Kuckes'755 teaches a method for elimination of disturbance fields (Col. 11, Line 3-9).

Claim 28/22: Kuckes'755 teaches a method for variation of the current supply to an electromagnet (Col. 9, Line 43-47), or an electromagnet being switched on and off (Claim 15).

Claim 29/1: Kuckes'755 teaches a method for the determination of the position in real time (Col. 2, Line 57-59).

Claim 30/6/5/1: Kuckes'755 teaches an apparatus determination of the flow rate or emission rate of a liquid [drilling fluid]. The invention of Kuckes'755 teaches using controlling the flow of the drill fluid into the drill stem. Pressure sensors [related to flow rate] detect the changes in flow of the drilling fluid (Col. 9, Line 22-29).

Claim 31/23: Kuckes'755 teaches a method of frequency modulation for variation of the magnetic field generated by the magnet (Col. 9, Line 35-59).

Claim 32/23: Kuckes'755 teaches a method for variation of the current supply to an electromagnet (Col. 9, Line 43-47), or an electromagnet being switched on and off (Claim 15).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 4 & 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuckes'755 (US Patent No. 5,258,755) and further in view of Bladen'820 et al. (US Patent No. 5,913,820).

Claim 4/1: Kuckes'755 fails to teach the sensor in the instrument axis and the magnet on the outside. However, Bladen'820 teaches magnetic field sensor disposed in instrument axis, and a magnet disposed outside the instrument axis (Col. 2, Line 36-

40). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kuckes'755 and Bladen'820 in order to achieve a surprisingly accurate estimate of the position of the sensor in a computationally simple manner (Col. 2, Line 66 – Col. 3, Line 2).

Claim 15/1: Kuckes'755 fails to teach an apparatus for emission of light beams, laser beams, radioactive beams, sound waves or ultrasound waves. However, Bladen'820 teaches using a magnetic positioning system in combination with a colonoscope (Col. 12, Line 15-44). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kuckes'755 and Bladen'820 in order to provide position location in situations where there is insufficient space for three coil orthogonal sensor as used in prior art position location systems (Col. 11, Line 54-57).

Claims 16/1: Kuckes'755 fails to teach an apparatus with optics or ultrasound imaging. However, Bladen'820 teaches an apparatus for recording optical images or ultrasound images (Col. 12, Line 64-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kuckes'755 and Bladen'820 in order to present the endoscopist with a convenient view of the path of the instrument (Col. 12, Line 67 – Col. 13, Line 2).

13. Claim 9 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuckes'755 (US Patent No. 5,258,755) and further in view of Kuckes'775 (US Patent No. 5,589,775).

Claim 9/6/5/1: Applicant's own admission explains that it is possible to determine the position and the roll angle in the prior art and listed US Patent No. 5,589,775 (Page 7 Paragraph 0028). While Kuckes'755 hints in US Patent No. 5,258,755 about finding the instantaneous angular position [roll angle], Kuckes'775 explains the process in more detail. Kuckes'775 teaches a roll angle of instrument is measured by a variable magnetic field component, which depends on the roll angle (Col. 4, Line 32-60). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kuckes'755 and Kuckes'775 in order to understand the relationship between the rotating magnetic field source and the magnetic field sensor (Col. 4, Line 32-33).

Claim 21/1: Kuckes'755 fails to teach shielding. However, Kuckes'775 teaches a gradual shielding of the magnet (Col. 9, Line 65 – (Col. 10, Line 11). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kuckes'755 and Kuckes'775 in order to give a good distance determination and provide a reference channel (Col. 10, Line 7-9).

14. Claim 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuckes'755 (US Patent No. 5,258,755), in view of Kuckes'775 (US Patent No. 5,589,775) and further in view of CreightonIV'196 (US Patent No. 6,537,196 B1).

Claim 10/9/6/5/1: Kuckes'755 and Kuckes'755 fail to sufficiently teach a reproducible deflection. However, CreightonIV'196 teaches an apparatus for providing a reproducible deflection of the magnet from its rotation axis (Col. 6, Line 7-11), wherein the reversing the magnetic field is considered a deflection. It would have been obvious

to one of ordinary skill in the art at the time of the invention to combine the teachings of Kuckes'755, Kuckes'775 and CreightonIV'196 in order to provide better access to the patient and better accommodate other equipment (Col. 5, Line 41-42).

Claim 11/9/6/5/1: Kuckes'755 and Kuckes'775 fail to teach an apparatus with means to interrupt the rotation of the magnet. CreightonIV'196 teaches means to interrupts the rotation of the magnet (Col. 6, Line 20-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kuckes'755, Kuckes'775 and CreightonIV'196 in order to provide better access to the patient and better accommodate other equipment (Col. 5, Line 41-42).

Claim 12/9/6/5/1: Kuckes'755 and Kuckes'775 fail to adequately teach magnetic elements which move in respect to one another. However, CreightonIV'196 teaches an apparatus with magnetic elements which move in respect to one another (Col. 5, Line 33-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kuckes'755, Kuckes'775 and CreightonIV'196 in order to avoid translating the assembly (Col. 5, Line 37-38). While Kuckes'755 hints in US Patent No. 5,258,755 about finding the instantaneous angular position [roll angle], Kuckes'775 explains the process in more detail. Kuckes'775 teaches a magnet shifted by a driver at a specific roll angle (Col. 4, Line 32-60). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kuckes'755 and Kuckes'775 in order to understand the relationship between the rotating magnetic field source and the magnetic field sensor (Col. 4, Line 32-33).

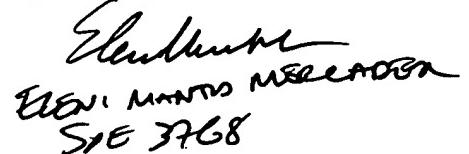
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Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- i. Haynor, David R. et al. System and Method to Determine the Location and Orientation of an Indwelling Medical Device. US Patent No. 6,263,230 B1. July 17, 2001.
 - j. Kawashima, Tomonao. Ultrasonic Diagnostic Apparatus and Ultrasonic Diagnostic Method. US Patent No. 6,755,791 B1. June 29, 2004.
 - k. Koch, Roger Hilsen. Magnetic Catheter Tracker and Method Therefor. US Patent No. 6,052,610. April 18, 2000.
 - l. Sugita, Kei et al. "Study of Time Dependent Magnetic Field Variation Due to Current Redistribution in Rutherford Cable." IEEE TRANSACTIONS ON APPLIED SUPERCONDUCTIVITY, VOL. 14, NO. 2. (JUNE 2004): 255-258.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Eleni Mantis Mercader
SPE 3768